K063007

510(k) Summary

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OCT 17 2006

Contact information:
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This 510(k) summary was prepared June/July, 2006, and finished 15 July, 2006.

Trade Name – PowertomeTM Periotome S100
Common name – periotome
Classification name – probe, periodontic (21CFR872.4565, Product Code EIX)
We are claiming substantial equivalence to a device made by B.T.I. BIOTECHNOLOGY INSTITUTE, S.L., Osseous Technologies of America, Karl Schumacher, and others, called a periotome.

Device description: The Powertome periotome is designed as an aid to dental professionals in the extraction of a tooth, or multiple teeth, from their socket. It is designed to minimize alveolar bone loss, thus providing an initial step in the preparation prior to placing dental implants, whose success rate is highly dependent on minimal (or no) bone loss. It functions by severing the periodontal ligaments that attach the cementum of the tooth to the alveolar bone, by use of different sized and shaped tips that provide the leverage and effect desired. These ligaments are one of two methods by which teeth stay in the jaw. The second function is to push the alveolar bone away from the tooth, thus disengaging the mechanical leverage the alveolar bone uses on the irregularity of the roots of the tooth to also help hold the tooth in place. Once the ligaments are cut, and the alveolar bone pushed away, the tooth extracts trivially.
Typical methods of extraction of a tooth are:

1. Use of forceps. The forceps grab the tooth, and the professional then twists the tooth in place, tearing the periodontal ligaments, and also expanding the alveolar bone. Once there is sufficient clearance, and the periodontal ligaments are detached, the tooth can be removed. This results in significant bone loss, and can be painful for the patient.
2. Use of a manual periotome: The periotome is inserted between the tooth and gum, and pushed between the tooth and bone until it meets resistance. The device can then be pushed toward the root of the tooth by moving the periotome back and forth, tangentially to the tooth surface.
3. Use of a manual periotome and mallet: The periotome is inserted between the tooth and gum, and pushed between the tooth and bone until it meets resistance. The device can then be tapped on the end with a mallet, driving it through the periodontal ligaments towards the root of the tooth. Often the use of the mallet is done with an assistant, who taps the end of the periotome with the mallet equal to the number of times the professional says "tap tap tap" (in this example, 3 taps with the mallet).
4. Our method is the same as #3, above, except that instead of an assistant tapping on the end of the periotome with a mallet, we use a small solenoid in the handpiece, which delivers a small but consistent force on the periotome tip, controlled in duration by the professional by use of a foot switch (for on/off control). The total delivered power for each stroke is controlled, and can be set by the professional.

This product was designed to simulate the action that is provided by the mallet, but to give greater control over the process, both from a safety (totally controlled by the professional) and effectiveness (controlled stroke allows the professional to easily determine when the tooth has been sufficiently loosened in it's socket). The materials used that come in contact with the patient are the same as used in the manual periotomes – wrought stainless steel. The tips employed are of the same general length, width, and depth as those currently used by manual periotomes.

Intended use: The intended use of this device is as an aid in the removal of teeth, due to caries(decay), trauma, orthodontic reasons, periodontal bone loss or malformation of the tooth. It is also intended to be used to remove teeth as part of the preparation for dental implants, where minimizing bone loss is critical.
All types of devices typically used in extractions, including forceps, periotomes, dental elevators, and even chisels, are Class I, exempt from 510(k). The specific indications for use have been taken from advertising done by various dental distribution or manufacturers, and, although not verbatim on our intended use, have very similar wording. Differences do not impact the safety, not the effectiveness of this device when used as labeled.

Technological characteristics: Our device does have different technological characteristics from the predicate device. The power source to cut through the periodontal ligaments and expand the bone are done either by manually forcing the tip through the ligaments, or with an external power source consisting of an assistant and a hammer (mallet), used to supply additional force to cut through the periodontal ligaments and expand the socket. To determine the amount of force, and do a comparison with our device, we tested the amount of force delivered by utilization of our device, and with a hammer, and also characterized typical numbers by interviewing professionals:

Characteristic	*Predicate Device*	*Powertome periotome*
Maximum amount of force/stroke	122 lb	90 lb
Minimum amount of force/stroke	16 lb	21 lb
Standard deviation force/stroke	27 lb	15 lb
Mean force/stroke	79 lb	52 lb
Frequency	200 milliseconds/stroke	50 milliseconds/stroke
Duration of impact	420 ms	70 ms
Force controlled by professional	No	Yes
Max/Min length of power[1] stroke	1/3 - 10"	.01" max., .01" min.

Clinical data: We have not used clinical data to support our claim of substantial equivalence.

Anecdotal data: Two dental professionals have been using prototype versions of the product. Neither practitioner wishes to return to the manual periotome with mallet, as the Powertome periotome provides significantly increased control over the outcome.

Conclusions:

Characteristic	*Predicate Device*	*Powertome periotome*
Success in cutting periodontal ligament	Yes, with verbal control	Yes, with electronic control
Success in expanding tooth socket by movement of alveolar bone	Yes, with verbal control	Yes, with electronic control
Repeatability	Low	High
Safety: Force controlled by professional	No	Yes

The Powertome periotome is as safe and as effective as the predicate device in performing it's indicated use.

1 mallet or solenoid

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2006

Westport Medical, Incorporated
C/O Ms. Michelle S. Lee
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K063007
Trade/Device Name: Powertome Periotome
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: September 29, 2006
Received: October 2, 2006

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

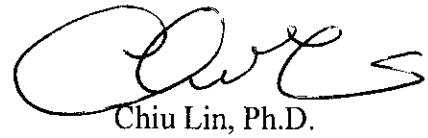
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
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Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K063007

Device Name: Powertome Periotome

Indications for Use: This device is to be used to expand the tooth socket to facilitate tooth removal, due to caries, trauma, orthodontic reasons, periodontal bone loss, or the malformation of the tooth, and/or to prepare the site for placement of endosseous dental implants or abutments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number K063007